DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 15, 2015

JJGC Industria E Comercio De Materiais Dentarios SA
c/o Kevin A. Thomas, Ph.D.
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K150199
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 13, 2015
Received: May 14, 2015

Dear Dr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150199

Device Name

Neodent Implant System

Indications for Use *(Describe)*

CM Alvim Acqua Implant
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

Facility Acqua Implant
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
The Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.

CM Anatomic Abutment, Exact Anatomic, Lateral Anatomic, and Lateral Anatomic Abutments
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K150199

510(k) Summary

JJGC Indústria e Comércio de Materiais Dentários SA

Neodent Implant System

May 13, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 - CIC Curitiba, Paraná, 81270-200, Brazil Telephone: +55 41 2169 4058 Fax: +55 41 2169 1043
Official Contact	Jacson Cambruzzi Head of Quality and Regulatory Affairs
Representative/Consultant	Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 (858) 792-1235 Fax +1 (858) 792-1236 Email kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

CM Alvim Acqua Implant
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

Facility Acqua Implant
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DEVICE DESCRIPTION

The purpose of this submission is to expand the Neodent Implant System components cleared under K101945, K123022, and K133592; these submissions included dental implants with a Morse taper (CM) abutment interface, mating abutments, abutment screws, and other associated components. The additions included in this submission are CM Alvim Acqua and Facility Acqua implants, and 17° angled anatomic abutments.

All of the subject device implants are threaded, self-tapping, root form, endosseous dental implants with Morse taper abutment interfaces. The CM Alvim Acqua implants are made from unalloyed titanium, Grade 4, conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).* The Facility Acqua implants are made from titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* All implants have the "Acqua" surface cleared in K133592. The Acqua surface begins with the traditional grit blasted and acid etched endosseous surface (branded "NeoPoros"), which is identical to that used on implants cleared in K101945 and K123022. The NeoPoros surface undergoes additional

processing that renders the surface hydrophilic. The CM Alvim Acqua implants are provided in 3.5, 4.3, and 5.0 mm diameters; each diameter is provided in 8, 10, 11.5, 13, and 16 mm lengths. The Facility Acqua implant is provided with a 2.9 mm diameter in 8, 10, 12, 14, and 16 mm lengths.

This submission includes four series of cement-retained abutments intended for single unit prostheses in the esthetic zone. Each series has scalloped margins to follow the gingival contour to provide better esthetic results with the final prosthesis. The series include CM Anatomic and CM Lateral Anatomic abutments, each without and with an internal indexing feature (branded "Exact") at the apical end of the Morse taper connection. All abutments are angled 17°, are provided in 1.5, 2.5, and 3.5 mm gingival heights, and are made from titanium alloy conforming to ASTM F136.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility, engineering analysis, and dimensional analysis. Animal histology data were presented comparing predicate devices to the subject devices implanted in sheep tibiae.

Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

Neodent Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K133592, Neodent Implant System, Neodent USA, Inc.;

K101945, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA; and

K123022, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA.

The primary predicate device is K123022. Reference predicates are K133492 and K101945.

The implants in this submission have similar designs and dimensions, use the same materials, and have the same surface as those cleared under K133592, K101945, and K123022. The CM Alvim Acqua implant design is identical to the design of the Alvim CM implant cleared in K101945. The Facility Acqua implant design is identical to the design of the Facility implant cleared in K123022. The Acqua surface treatment is identical to that cleared in K133592.

The abutments in this submission have similar designs and are made from the same material as those cleared under K101945 and K123022.

The subject device implant and abutments have similar packaging and are sterilized using the same processes as described in K133592, K101945, and K123022.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new questions of safety or effectiveness.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.